

REMARKS

Claims 2-3 and 5-10 are pending in the application. Claim 6 has been cancelled by this amendment. New claims 11-14 have been added to the application. Therefore, claims 2, 3, 5, and 7-14 are at issue.

New claims 11-14 recite specific neuropathies treatable by the method of claim 5. Support for new claims 11-14 can be found in the English-language translation of the specification at page 1, lines 7-10. It is submitted that new dependent claims 11-14 are patentable for the same reasons set forth below that independent claim 5 is patentable.

Claims 2, 3, and 5 stand rejected under 35 U.S.C. §112, first paragraph, as not being enabling. In particular, the examiner contends that the specification is enabling with respect to treating "neuropathy," but not "neuropathies." In response, applicant has amended claim 1 reciting "an autonomous neuropathy." Applicant also has added new claims 11-14 directed to degenerative, toxic, metabolic, and ischemic neuropathy. In view of the amendment to claim 5, it is submitted that all pending claims fully comply with 35 U.S.C. §112, first paragraph, and that the rejection should be withdrawn.

Claims 2, 3, and 5-10 stand rejected under 35 U.S.C. §102(e) as being obvious over Graham U.S. Patent No. 6,075,028 ('028). In view of the amendments to the claims as suggested by the examiner, it is submitted that this rejection has been overcome and should be withdrawn. It also should be noted that the '028 patent is directed to Tourette's Syndrome and other central nervous system disorders. Therefore, the

amendment to claim 5 reciting "in need thereof" is merely to facilitate prosecution and to make the claims more clear.

Claims 2, 3, 5, and 9 stand rejected under 35 U.S.C. §102(e) as being anticipated by DuBois U.S. Patent No. 6,399,601 ('601). Claims 6-8 and 10 stand rejected under 35 U.S.C. §103 as being obvious over the '601 patent in view of a Gentile publication. For the reasons set forth below, it is submitted that these rejections are in error and should be withdrawn.

Claim 6, which was not included in the anticipation rejection, has been cancelled and the features of claim 6 incorporated into independent claim 5. Support for this amendment to claim 5 can be found in originally filed claim 6. In view of this amendment to claim 5, it is submitted that the rejection of claims 2, 3, 5, and 9 as being anticipated by the '601 patent under 35 U.S.C. §102(e) should be withdrawn.

With respect to the rejection of the claims under 35 U.S.C. §103, the '601 patent is directed to compounds of Formula I that *differ substantially* from sildenafil and are useful in the treatment of diabetes and in the treatment of diabetic complications ('602 patent, column 23, line 63 through column 24, line 2). The '601 patent goes on to state that a litany of other drugs having several different modes of action can be used in conjunction with the compounds of Formula I to treat diabetes (column 24, line 18). This long list includes sildenafil as an agent to treat diabetes.

The '601 patent fails to teach or suggest that sildenafil can be used alone, without a compound of Formula I of the '601 patent, to treat diabetes. In

fact, throughout the '601 patent, it is taught that a compound of Formula I is necessary for the treatment. Notably, the '601 patent also teaches that sildenafil treats diabetes, not diabetic complications.

In particular, the '601 patent at column 23, line 63 through column 24, line 17 states that a compound of Formula I can treat diabetes and complications of diabetes. The '601 patent also states that a compound of Formula I can be used with a second agent useful in the treatment of diabetes or obesity (column 24, lines 8-12). Sildenafil is not taught in the '601 patent as a drug to treat complications of diabetes, but to actually treat the disease (see column 24, lines 18-19 and 38).

In contrast to the '601 patent, the present method utilizes sildenafil to treat neuropathies, not to treat diabetes. Note in Examples 1 and 2 of the specification that the patients were administered sildenafil to achieve an improvement of symptomatic pain and the symptoms and complications from diabetes, but not the disease itself.

As recognized by the examiner, the '601 patent is absolutely silent with respect to an amount of sildenafil needed to treat diabetes, let alone an amount to treat an autonomous neuropathy. In addition, even if the amount of sildenafil necessary to treat diabetes was disclosed, this amount would not necessarily teach or suggest the amount of sildenafil needed to treat an autonomous neuropathy. The Gentile publication does not overcome this significant deficiency of the '601 patent. The Gentile publication merely states that autonomic diabetic neuropathy of the alimentary

canal takes several forms, and that diabetics should be aware of bile disorders. The Gentile publication is totally silent with respect to using sildenafil to treat a neuropathy, let alone disclosing a sildenafil dose required to treat a neuropathy.

In summary, a person skilled in the art, after reading the '601 patent and the Gentile publication, in combination, would not have considered administering sildenafil in a method of treating an autonomous neuropathy, as is recited in claim 5. The references, alone or in combination, fail to provide any motivation for a person skilled in the art to consider using sildenafil in the claimed amounts to treat a neuropathy. Therefore, it is submitted that all pending claims are patentable over the '601 patent in view of the Gentile publication, and that the rejection should be withdrawn.

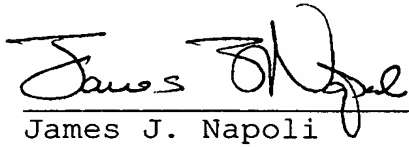
In summary, it is submitted that all pending claims are in a form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

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By

A handwritten signature in dark ink, appearing to read "James J. Napoli", is written over a horizontal line.

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